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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/930,591	08/15/2001	Matti Sallberg	TRIPEP.028AUS	3174

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EXAMINER	
LI, BAO Q	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 09/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/930,591	SALLBERG, MATTI	
	Examiner	Art Unit	
	Bao Qun Li	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,10,11,27,28,31 and 33-75* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2, 27-28, 33-34, 47-75* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 09/13,02; 10/02,02; 02/12,03; 12/12/03; 03/17,03; 06/28,04; and 06/21,04
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amendment filed on 07/06/2004 has been acknowledged. Claims 1-8, 27-28 have been amended. Claims 9, 12-26, 29-30 and 32 have been canceled. New claims 33-75 have been added. Claims 1-8, 10-11, 27-28, 31 and 33-75 are pending.

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-7, 10-11, 31 in the reply filed on July 06,2204 is acknowledged. The traversal is on the ground(s) that claim 8 should be rejoined with the elected group I since the nucleic acid of claim 1 encodes the peptide of SEQ ID NO: 2 in claim 2 as disclosed by the specification on pages 7 and 9.

2. Applicants' argument has been fully considered. After sequence alignment, claim 8 and its depended claims 45, 54, 62, and 70 are rejoined with elected group I.

3. Claims 1-8, 10-11, 27-28, 31 and 33-75 are considered before the examiner.

Specification

4. The disclosure on page 63 is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

5. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter, an adjuvant in claim 74. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). In the instant case, the claim 74 drawn to a composition comprising the isolated nucleic acid, an adjuvant in addition to ribavirin (claim 75 considered). However, the current specification does not have any description for the recited adjuvant except the ribavirin. The Examiner has noticed that the priority document of provisional application No. 60,229,275 has a disclosure of an additional adjuvant in its claims, while the current application still needs to be amended by including the subject matter in claim.

Priority

6. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

7. The recitation of a U.S patent application No. 09/705,547 of lines 7-8 on page 1 in the specification is improperly for listing the non-provisional application No. 09/705,547 as its priority document without specifying what the relationship between the current application and the referencing application is. An appropriate correction is required.

8. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional application No. 60,225,767 upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claim 75 of current application. Because the provisional application No. 60,225,767 only teaches a composition comprising a nucleic acid sequence of SEQ ID NO: 1 in combination with ribavirin for inducing an enhanced immune response, it does not have any disclosure of a composition comprising a nucleic acid sequence of SEQ ID NO: 1, ribavirin plus another adjuvant. Therefore, the domestic priority of claim 75 in the current application based on the provisional application No. 60,225,767 is denied.

Claim Rejections - 35 USC § 101

9. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

10. The invention of claims 34, 36, 38, 40, 42, 44, 46 and 72 are directed to non-statutory subject matter. There is no recitation of an isolated or a transfected in front of the claimed cell. Therefore, the claimed cell could read on naturally occurring materials, which are considered to be non-statutory and non-patenable subject matter within the scope of 35 U.S.C. 101. See Official Gazett, 1077 O.G. April 21, 1987. It is recommended that the claim incorporate the claim language, " transfected or isolated " to overcome this rejection.

11. In the instant case, because the claimed nucleic acid sequence can read on a nature product of a HCV virus isolate, especially considering that claims use an open language " comprising" to describe the claimed nucleic acid molecule, the nucleic acid molecule read on a nucleic acid sequence encoding the whole genome of an hepatitis C virus strain and therefore, an infected cell in a patient may harbor such virus genome.

Claim Rejections - 35 USC § 112

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 55-70 and 74-75 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for having a composition comprising a DNA vector inserted with a nucleic acid molecule consisting of the nucleic acid sequence of SEQ ID NO: 1, which encodes the amino acid sequence of SEQ ID NO: 2 or a fragment thereof in combination of ribavirin and/or an adjuvant for inducing an enhanced immune response, does not reasonably provide enablement for having a composition comprising any or all nucleic acid sequence comprising the isolated nucleic acid sequence of SEQ ID NO: 1 or fragment thereof in combination with ribavirin or an adjuvant capable of being an immunogenic composition in a host, The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

14. The test of scope of the enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the application coupled with information known in the art would undue experimentation (See United States v. Theketronic Inc., 8USPQ2d 1217 (fed Cir. 1988). Whether undue experimentation is required is not based upon a single factor but rather a conclusion reached by weighting many factors. Theses factors were outlined in Ex parte Forman, 230 USPQ 546 (Bd. Pat. App. & Inter. 1986) and in re Wands, 8USPQ2d 1400 (Fed. Cir. 1988). These factors include the following:

15. 1) & 2) State of art and unpredictability of the filed. State of art teaches that a DNA vaccine is considered as a plasmid or vector carrying a nucleic acid that encodes a pathogenic antigen peptide or polypeptide being able to induce an immune response after it is administered into a host. However, the state of art does not teach that a naked DNA without any carried vector can be used as an immunogenic composition because it does not have the expression machinery. It is also unpredictable if the injected nucleic acid molecule encoding the whole HCV genome

because the claims use open language "comprising", which results in the claimed nucleic acid molecule read on a whole virus genome. The host cell infected or transfected with a HCV whole genetic material produces infectious HCV in vitro or in vivo as evidenced by Lohman et al. (Science 1999, Vol. 285, pp. 110-113, see page 110) and Forns et al. (PNAS 2000, Vol. 97, pp. 13318-13323, see pages 13318-13320).

16. 3) & 4) Number of working examples and amount of guidance. The specification only teaches a composition made by vector carrying the claimed SEQ ID NO: 1 or fragment thereof plus ribavirin (See disclosure at lines 7-18 on page 65 of specification), which is able to induce an enhanced immune response. The specification does not teach any or naked DNA without vector is able to express an antigen and induce an immune response in a host.

17. 5) Scope of the claims. The claims broad read on a composition comprising any nucleic acid molecule comprising at least 50 consecutive nucleic acid of sequence of SEQ ID NO: 1, which would read on a whole genomic sequence of an isolated HCV.

18. 6) & 7) Nature of the invention and level of the skill in the art. The invention involves a complex and unpredictable DNA immunization. The level is high.

19. Given the above analysis of the factors, which the courts have determined, are critical in asserting whether a claimed invention is enabled, it must be considered that the skilled artisan would have to conduct undue and excessive experimentation in order to practice the claimed invention.

Double Patenting

20. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969). A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or

provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

21. Claims 27-28, 47-74 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 21 and 28 of copending Application No. 09/929,955.

22. Claims 21 and 28 of application "955" are directed to an immunogenic composition comprising an HCV nucleic acid comprising a sequence of SEQ ID NO: 16 and a ribavirin. The rejected claims 27-28 and 44-74 of current application are directed to a composition comprising an HCV nucleic acid sequence consisting of SEQ ID NO: 1 or a nucleic acid molecule comprising at lest 50 consecutive nucleic acids of SEQ ID NO: 1 or a nucleic acid sequence encoding the peptide of SEQ ID NO: 2, and adjuvant, wherein the adjuvant in claims 63-69 are further limited to ribavirin. By sequence comparative analysis, the claimed polynucleotide of SEQ ID NO: 1 or nucleic acid sequence that encodes the peptide of SEQ ID NO: 2 is 100% is found to be identical to the SEQ ID NO: 16. Moreover, claims 21 and 28 also claim to contain ribavirin in the composition, which function as an adjuvant. While the scope of claimed nucleic acid sequence in "955" is broader than the rejected claims of current application in that it may be or may not be larger in size than the currently claimed polynucleotide of SEQ ID NO: 1 or nucleic acid sequence that encodes the protein of SEQ ID NO: 2, it certainly comprises the nucleic acid molecule of SEQ ID NO: 1 or fragment thereof or the nucleic acid sequence that encodes the protein of SEQ ID NO: 2 in its frame. Thus, claimed invention of current application encompass in the scope of claims 21 and 28 of application "955'. The claims 21 and 28 anticipate the rejected claims 27-28, 47-74.

23. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

24. Claims 8, 45, 46 and 54 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 and 38-41 of copending Application No. 10,307,047.

25. In the instant case, claims 8, 45, 46 and 54 are drawn to an isolated nucleic acid comprising a sequence encoding a peptide of the sequence of SEQ ID NO: 2, a vector , a cell and a composition comprising same. Claims 1-7 and 38-41 of application "047" are directed to an isolated nucleic acid molecule and a cell , and a vector and a composition comprising at least 50 consecutive nucleotide of SEQ ID NO: 35, which has 100 homology to the nucleic acid sequence of the rejected claims 8, 45, 46 and 54. While the scope of claims are not identical, they are overlapping each other. Therefore, claims 1-7 and 38-41 anticipate the claims 8, 45-46 and 54.

Claim Rejections - 35 USC § 102

26. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

27. Claims 2, 33, 34 and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Brechot et al. (US patent No. 5, 879,904A).

28. Brechot et al. teach an isolated oligonucleotide DNA sequence of SEQ ID NO: 6, an expressing vector and a host cell comprising the DNA sequence, wherein the SEQ ID NO: 6 comprises consecutive 61 nucleic acids of claimed polynucleotide sequence of SEQ ID NO: 1 in current application. Brechot et al. also teach that the isolated DNA sequence or fragment thereof can be used as a probe and a kit comprising the probe (lines 7-9, 31-47 on col. 2 and lines 7-7 on col. 3 and claims 2-7). Because a kit comprising the probe and other reagents is a composition. The claims are anticipated by the cited reference.

29. Claims 2, 33, 34 and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Houghton et al. (US patent No. 5, 885,799A).

30. Houghton et al. teach three isolated oligonucleotide DNA sequences, SEQ ID NO: 69, SEQ ID NO: 71 and SEQ ID NO: 85. All of them comprise 55-consesutive nucleic acids of the claimed SEQ ID NO: 1. The nucleotide sequences of SEQ ID NO: 85 is also inserted into an expressing vector and transfected into a yeast host cell (See lines 16-17 and lines 37-38 on col. 2, and Example 8 & 9 on col. 21-22). While the reference does not explicitly indicate the nucleic acid sequence, such as SEQ ID NO: 71 or SEQ ID NO: 85 are in a composition, these sequences are inherently in a composition because during the process of isolating and using them. It is well known in the art that the DNA sample used for any ligation or restriction reactions must be dissolved by a solvent, such as H2O or TE buffer (Tris/EDTA buffer) and the reaction must be carried out in a mixture of a liquid phase. For example, Houghton et al. teach that the nucleic acid sequences SEQ ID NO: 71 (See line 16-17 on col. 2 and lines 35-63 on col. 17) and SEQ ID NO: 85 are ligated under a standard buffer condition (Se lines 17-31 on col. 11 and lines 37-38 on col. 2 and lines 19-29 on col. 22) to generate a construct encoding HCV protease, which is further ligated into expressing vectors, such as pGEM4Z and pBR322. The vector C7fC20cC300 is further constructed and tansfected into a yeast host cell to express as a fusion protein (See lines 19-29 on col. 22). All of the buffers for carrying on the ligation or restriction reactions are indicate the DNA is in a composition. Therefore, the claimed invention is anticipated by the cited reference.

Claim Rejections - 35 USC § 102

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

31. Claims 2, 33, 34 and 48 are rejected under 35 U.S.C. 102(e) as being anticipated by Yanagi et al. (US patent No. 6,153,421A)

32. Yanagi et al. disclose an isolated nucleic acid molecule of SEQ ID NO: 6, which encodes a human hepatitis C virus clone H77, wherein the nucleic acid sequence comprises a sequence having a consecutive 52 nucleotides of claimed nucleic acid sequence of SEQ ID NO: 1 in the frame. Yanagi et al. also teach a method of constructing the full length H77 cDNA clone and a vector comprising the cDNA and a cell transfected with the cDNA. During the process of making, purifying as well as using the cDNA construct, the DNA sample is dissolved in a solution, which is a composition comprising the isolated cDNA and DNA dissolving buffer (See Claims 9-12, 14, 23 and col. 17 and 18). Therefore, the claimed invention is anticipated by the cited reference.

33. Claims 2, 33, 34 and 48 are rejected under 35 U.S.C. 102(e) as being anticipated by Chien et al. (US patent No. 6,150,087A)

34. Chien et al. disclose several isolated nucleic acid molecule encoding a human hepatitis C virus genome, including SEQ ID NOs: 53, 65, 74, 88, 122, 137 and 176. All of them comprise a nucleic acid sequence having a consecutive 55 nucleic acids of the claimed sequence of SEQ ID NO: 1 in the frame. Chien et al. also teach the composite of cDNA can be constructed into an expressing vector for expressing the antigenic polypeptides in a host cell or be prepared as hybridization probes as well as kits containing the sequences or fragment thereof in suitable containers (See lines 42 on col. 45 through line 61 on col. 46 and lines 1-64 on col. 5). Because the kit comprising the probe is a composition, the claimed invention is anticipated by the cited reference.

Conclusion

Claims 1, 3-8, 10-11, 31 and 71 are deemed free of prior art, given failure of the prior art to teach or reasonably suggest an isolated nucleic acid consisting of or comprising at least 100 consecutive nucleic acid sequence of SEQ ID NO: 1 or a nucleic acid sequence comprising a sequence encoding a peptide of the SEQ ID NO: 2.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 7:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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09/15/2004

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